# Adding remote ultrasound "knobology" control to remote just-in-time telementored trauma ultrasound: a randomised controlled trial

Recruitment status	Prospectively registered		
No longer recruiting	[] Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
<b>Condition category</b> Injury, Occupational Diseases, Poisoning	Individual participant data		
	Recruitment status No longer recruiting Overall study status Completed Condition category Injury, Occupational Diseases, Poisoning		

### Plain English summary of protocol

#### Background and study aims

Traumatic injury remains the leading cause of potentially preventable death in the Western world, especially in the Arctic, and is one, if not the most feared, pathology in Space Medicine. Resuscitative ultrasound is becoming a universal tool in emergency medicine that can capture a vast array of injuries and deranged physiology in the critically injured. An unfortunate practical reality however, is that ultrasound is very user dependant. Space Medicine has led the innovation however, in using advanced telecommunications to allow experts not at the scene of the trauma (remote expert) to guide non-experts to use on-scene ultrasound equipment to get clinically meaningful images. Furthermore, the Trauma Services group at the University of Calgary has led the world in examining the use of this technology in a clinical setting on earth. The Ultrasonix Corporation, under contract to the Canadian Space Agency (CSA), has developed an advanced Graphic User Interface (GUI) which allows a expert to control the ultrasound settings of a Ultrasonix Ultrasound remotely and to communicate with the non-expert user over a unique voice and video connection. A consistent finding of this experience has been the sentiment that being able to transfer the responsibility of controlling the ultrasound settings (knobology) from the on-site inexperienced user to the remote expert. The aim of this study is to test whether the use of a remote controlled GUI improve the usefulness of emergency "just-intime" remote telementored ultrasound as measured by examining the accuracy of the examination

#### Who can participate?

Firefighters from the city of Edmonton that have not had any prior experience with trauma ultrasound.

#### What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 perform a telementored ultrasound examination on an ultrasound phantom (a training model that gives realistic ultrasound images when scanned) to which fluid has been added. Those in group 2 perform a telementored ultrasound examination on an ultrasound phantom to which fluid has not been added. All participants are mentored by remote ultrasound experts who can view their

hand movements and provide 2-way communication. The intervention being randomized is the remote control of the ultrasound machine "knobology" by the remote mentor or not which is randomly assigned. The accuracy of the mentored examination is determined by the known "truth" regarding the volume of fluid added to the phantom. The time needed to complete the examination is also recorded with and without GUI assistance. All volunteers and remote mentors are asked to complete questionnaires for each examination in which all responses will be anonymous, regarding how useful they found the technique and the GUI, any suggested modifications to the GUI, and other general comments.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? Foothills Medical Centre, Calgary (Canada)

When is the study starting and how long is it expected to run for? October 2014 to March 2015

Who is funding the study? Canadian Space Agency

Who is the main contact? Professor Andrew Kirkpatrick andrew.kirkpatrick@albertahealthservices.ca

# **Contact information**

**Type(s)** Scientific

**Contact name** Dr Andrew Kirkpatrick

**Contact details** Trauma Services 1403 29 St NW Calgary Canada T2N 2T9 4039442888 andrew.kirkpatrick@albertahealthservices.ca

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

20949

# Study information

Scientific Title

Medical ultrasound remote access/control interface testing requirements for a graphic user interface (GUI)

### **Study objectives**

The aim is to test the usefulness of a remote ultrasound examination that utilizes a graphic user interface to assist with the knobology of the remote ultrasound machine.

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** University of Calgary Office of Medical Bioethics, 06/07/2007, ref: 20949

**Study design** Randomised controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Community

**Study type(s)** Diagnostic

### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

### Health condition(s) or problem(s) studied

Trauma Resuscitation

### Interventions

Pre-hospital responders unfamiliar with trauma ultrasound will be randomized to perform a telementored ultrasound examination on an ultrasound phantom to which fluid has been randomly added or not. They will be mentored by remote ultrasound experts who can view their hand movements and provide 2-way communication. The intervention being randomized is the remote control of the ultrasound machine "knobology" by the remote mentor or not which will be randomly assigned

Intervention Type

Device

**Phase** Not Applicable

#### Primary outcome measure

The accuracy of the mentored examination to detect any free fluid within the phantom (Binary yes/no determination) with and without GUI assistance.

#### Secondary outcome measures

The relative user satisfaction will be assessed using a previously verified post-examination satisfaction survey with the Likert scores compared for those using the GUI versus not.

**Overall study start date** 29/10/2014

**Completion date** 30/03/2015

# Eligibility

#### Key inclusion criteria

1. Pre-hospital care provider

2. Willingness to participate

3. Command of English

**Participant type(s)** Health professional

#### Age group

Adult

## Sex

Both

**Target number of participants** 100

**Total final enrolment** 101

### Key exclusion criteria

Any prior experience with ultrasound
Unwilling to participate
Unable to speak English

**Date of first enrolment** 29/10/2014

**Date of final enrolment** 30/05/2015

# Locations

**Countries of recruitment** Canada

Study participating centre Foothills Medical Centre Trauma Services 1403 29 St NW Calgary Canada T2N 2T9

# Sponsor information

**Organisation** Canadian Space Agency

### **Sponsor details**

Operational Space Medicine Space Exploration 6767, Route de l'Aéroport Longueuil (St-Hubert), Quebec Canada J3Y 8Y9 (450) 926-4734 pat.sullivan@asc-csa.gc.ca

### Sponsor type

Government

Website www.asc-csa.gc.ca

ROR https://ror.org/03a1gte98

# Funder(s)

**Funder type** Government **Funder Name** Canadian Space Agency

Alternative Name(s) Agence Spatiale Canadienne, CSA, ASC

**Funding Body Type** Government organisation

Funding Body Subtype National government

**Location** Canada

# **Results and Publications**

### Publication and dissemination plan

We intend to produce a peer reviewed manuscript for presentation at a major trauma conference followed by submission to a peer reviewed Journal

Intention to publish date

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Available on request

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016	25/06/2020	Yes	No